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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,634	03/01/2002	Henry Yue	PF-0738 USN	9443

7590 05/26/2004

Incyte Genomics Inc
Legal Department
3160 Porter Drive
Palo Alto, CA 94304

EXAMINER

PATTERSON, CHARLES L JR

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,634

Applicant(s)

YUE ET AL.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-11, 13, 15-17, 19, 22, 25 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) 1, 2, 10, 16, 17, 19, 22, 25 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-7, 9, 11, 13, 15, 29 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Applicant's election with traverse of groups 13-24, claims 3-7, 9, 11, 13, 15 and new claims 29-30, limited to SEQ ID NO:12 and 26 in the paper filed 3/17/04 is acknowledged. The traversal is on the ground(s) that: (1) Unity of invention must be applied in national stage applications and that unity of invention "exists at least as between claims drawn to polypeptide sequences SEQ ID NO:2-9 and 11-24...and as to claims drawn to polynucleotide sequences which encode those polypeptide". (2) The polypeptides and polynucleotides of groups 1-24 have a special technical feature and the reference cited in the PCT Search report (Acc. No. 015416) teaches a genomic DNA and that this teaching is not prior art reading on the instant claims. (3) The Examples Of Nucleotide Sequence Claims in MPEP § 803.04 states that "the ten nucleotide sequences selected in response to the restriction requirement and any other claimed sequences which are patentably indistinct therefrom will be examined", and therefore ten sequences must be examined using Markush practice to examine sequences until prior art is found.

This is not found persuasive because:

(1) It is maintained that the examiner has followed unity of invention practice. MPEP 1805(A) states that "[I]f, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is no link remaining, an objection of lack of unity (that is, arising only after assessment of the prior art) may be raised. Similar considerations apply in the case of a genus/species or combination/subcombination situation". (2) Assuming that the cited prior art does teach a genomic DNA as stated by applicant, claim 1 claims "an immunogenic fragment of a polypeptide having" the cited sequences and claim 3 is drawn to a polynucleotide encoding the polypeptide. The reference then reads on at least

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claim 3 since the genomic sequence encodes a fragment of the polypeptide. An immunogenic fragment is of no particular length so that any length fragment will read on the claim. (3) In the first part of MPEP § 803.04 it is stated that "in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction". It is further stated that in some cases less than ten sequences may be examined if they are complex. One sequence is "up to ten" and it is maintained that since the nucleotides encode completely different structural proteins and are themselves structurally different, only one nucleotide sequence should be examined. MPEP 803.02 states that "[b]roadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility". The instant nucleotides do not share a substantial structural feature as they have different sequences (structures) and furthermore they encode structurally different proteins with different structures (sequences) which causes different secondary and tertiary structures. It is maintained that they are thus properly restricted.

Mori, et al. (V) and Lee, et al. (W) are added as references that teach the polypeptide of group I and are further reasons that there is not unity of invention for the instant claims, absent very convincing proof to the contrary.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-2, 10, 16-17, 19, 22, 25 and 28 and claims 3-7, 9, 11, 13, 15 and new claims 29-30, not limited to SEQ ID NO:12 and 26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Appli-

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cant timely traversed the restriction (election) requirement in the paper filed 3/17/04.

Applicants state that claims 12, 14, 18, 20, 24, 26 and 27 were cancelled in the Transmittal filed 3/1/02 and that the examiner has incorrectly numbered the groups because he did not omit SEQ ID NO:10 and 24 from the groups. The transmittal canceling the instant claims was not found in the application file and the examiner agrees that he apparently misnumbered the groups because of failure to omit SEQ ID NO:10 and 24. He agrees that the new groups outlined by applicants should have been the groups in the restriction. The examiner will examine claims 3-7, 9, 11, 13, 15 and new claims 29-30, limited to SEQ ID NO:12 and 26.

Claims 3-5, 9, 11 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-5, 9 and 11 are confusing in that they are drawn to claims not elected for prosecution and/or sequences not elected for prosecution.

Claim 15 is indefinite in the recitation of "optionally" on line 7. It is not known whether this is meant to be a limitation on the claim or simply illustrative.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and

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use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-7, 9, 11, 13, 15 and 29-30 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The specification teaches that SEQ ID NO:26 was isolated from human colon tumor tissue (Table 4). SEQ ID NO:12, which is allegedly the protein that is encoded by SEQ ID NO:26, is "homologous" to an "asparaginase related protein" from *Neurospora crass* (Table 2). There is no specific assertion in the specification that SEQ ID NO:12 is an asparaginase and thus there is no specific and substantial asserted utility that SEQ ID NO:26, which supposedly encodes the protein, has any specific and substantial asserted utility. Applicants discuss such possible utilities as microarrays, but this is not a specific and substantial utility for SEQ ID NO:26. Apparently the protein corresponding to this sequence has not been isolated and assayed for any biological activity.

Applicants submitted an IDS on 3/17/04 that shows the sequence of a protein that is stated to be "related to asparaginase" from *Neurospora crassa* and one that has "regions of weak similarity to 1-asparaginase" from *Arabidopsis thaliana*. Although there is no disclosure of how similar these proteins are to SEQ ID NO:12, the examiner found them in a sequence search and the query matches are 21.1% and 22.6%, respectively. This, is not a high enough percentage identity for one of ordinary skill in the art to conclude that the instant sequence is that of asparaginase, even assuming that the disclosures in the databases have been tested and are true, which is not assumed. The instant two protein sequences have been so characterized by their authors and presumably no further characterization has been done. Therefore

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it is maintained that there is nothing probative concerning the identity of the proteins in the two references.

Claims 3-7, 9, 11, 13, 15 and 29-30 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 11, 13, 15 and 29-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to a polynucleotide that is 70% identical with SEQ ID NO:26 and/or has at least 60 contiguous nucleotides of SEQ ID NO:26. The specification contains no guidance as to what nucleotides can be changed, added or deleted to SEQ ID NO:26 and still have the same properties as the sequence. Presumably no nucleotides can be changed and the sequence still have the same properties. The requirement of claim 29 that the polynucleotide have at least 60 contiguous nucleotides of SEQ ID NO:26 reads on polynucleotide molecules that consist of 60 nucleotides from anything whatsoever having 60 contiguous nucleotides, since the word "comprising" is used. The molecule could be from a completely unrelated gene as long as it met these characteristics. The specification does not teach one how to make polynucleotides of this scope and therefore one of ordinary skill in the art

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would not know how to make and/or use the claimed invention within the scope of the instant claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Evans, et al. (U). The instant reference apparently teaches the genomic DNA encoding at least an immunogenic fragment of SEQ ID NO:12, absent very convincing proof to the contrary.


Claims 3, 6-7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans, et al. (U). The instant reference has been characterized *supra*. It would have been obvious and well within the skill level of one of ordinary skill in the art to link a promoter to the polynucleotide, put this into a host cell and produce a polypeptide by using a host cell containing the polynucleotide, absent unexpected results.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
May 25, 2004